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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,865

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Christian Paulus

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EXAMINER

SALZMAN, KOURTNEY R

ART UNIT

PAPER NUMBER

1795

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,865	Applicant(s) PAULUS ET AL.	
	Examiner KOURTNEY R. SALZMAN	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>September 13, 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This is the first office action on the merits for application 10/551,865. This application is the 371 national stage application of PCT/DE04/00690, claiming priority to German document 10315080.3, filed April 2, 2003.
2. Claims 1-28 as originally filed in the PCT have been canceled.
3. Claims 29-56 are currently pending and have been fully considered.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
5. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 29-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a. Claim 29 is rendered indefinite as the device from the fourth limitation, lines 14-16, is described as needing to maintain "constant a ratio of electrical currents flowing at the operating electrode and the additional electrode", an electrical functionality. However, claims 42 and 47 put forth conflicting descriptions as to what the device can be in terms of functionality, stating that both an "insulating device" or analyte container and "electrical circuit" can function as the device of the claim. It is unclear to the examiner how both could function for this purpose. For this reason the claims are rendered indefinite.
- b. Claim 33 is indefinite because it states the piece modified to be "monolithically integrated" to be "that is". It isn't clear what piece is modified. However, in the interest of compact prosecution, the examiner has examined the "that is" in this rejection of the claim to be the "operational electrode is". Please correct.
- c. Claim 38 recites the limitation "wherein capture molecules" in the first to second lines of the claim. There is insufficient antecedent basis for this limitation in the claim as "capture molecules are not discussed in claims 29 or 36. However, in the interest of compact prosecution, the examiner has examined, for the purpose of this action, claim 38 to be dependent on claim 38. Please correct.
- d. Claim 47 recites, in the second to third line, for the device to be an insulation device arranged "such that it electrically insulates the electrolytic analyte". However, it is indefinite what the device is insulating the analyte from, as the figures of the instant application show the "insulating device" 709 to

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contain the analyte and put the analyte in contact with the electrically conductive electrodes. Furthermore, if the intention, as expressed in claim 29 and addressed in the 112 rejection of that claim above, is for the device to maintain electrical current flow, it is unclear how the device (as it is insulating) is to do so. However, in the interest of compact prosecution, the examiner has examined, for the purpose of this action, the insulating device to insulate the analyte from an exterior environment. Please correct.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 29-42 and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by FREY et al (WO 02/033397, the citations provided in this rejection are from the English translation of this document PG PUB 2004/0041717. It has been well established that English language equivalents of foreign documents are accepted forms of translation.).

Regarding claim 29, FREY et al teaches sensor arrangement 1400 comprising a working electrode 1403, additional electrode 1404 and an operating circuit 902 or 1402 maintains a potential difference (as described in 234 and 235 for example). A constant ratio between the potential at the working electrode and additional electrode is maintained because due to the connection of the two, as this is a

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system of two electrodes, the potential at both electrodes must be the same magnitude. Whether this device is an electric circuit shown as 1402 or 902 (as required by claim 42) or an insulating device which is shown as the container of 1408 (as required by claim 47), the broad interpretation of the device is shown in multiple places and interpretations. Furthermore, the condition of operation requiring a constant ratio of the potentials at each electrode is an operating condition and therefore does not impart any structural limitations on the apparatus. As the claims are to a sensor arrangement or apparatus, the examiner would like to direct attention to MPEP 2114 which states the manner of operation of the device does not differentiate an apparatus claim from the prior art.

Regarding claims 30 and 31, the claims are directed to the analyte to be detected, not the apparatus itself, therefore no structure is imparted to the apparatus or sensor arrangement, by the requirement of the analyte to be bound to substances with two different redox potentials. Furthermore, claim 31 is directed to a method of operation of the sensor arrangement. The sensor arrangement, due to the use of controllable voltages, is able to operate in the condition required in claim 31. However, as the claims are to a sensor arrangement or apparatus, the examiner would like to direct attention to MPEP 2114 which states the manner of operation of the device does not differentiate an apparatus claim from the prior art.

Regarding claim 32, FREY et al teaches an output in paragraph 122 and as reference number 1417 in figure 16.

Regarding claim 33, figure 16 of FREY et al also teaches the electrodes, at least a portion of the arrangement, to be shown on the substrate 1405.

Regarding claim 34, figure 16 of FREY et al also teaches the electrodes, at least a portion of the arrangement, to be shown on the substrate 1405, while the bonded electrode portions are shown external to the substrate.

Regarding claims 35-40, there is no structural difference imparted in these discrete sensors which structurally distinguishes them from each other in terms of the components of the arrangement as stipulated in claim 29 from which they depend. Moreover, FREY et al teaches a biosensor (where enzymes are reduced or oxidized) in paragraphs 68, 69 and 77 to fulfill claims 35-37 and 40.

Regarding claim 38, figure 16 shows the immobilized molecules 1409 at the working electrode. Regarding claim 39, redox cycling is discussed as a use for the sensor in paragraph 73.

Regarding claim 41, figure 16 shows both electrodes to be around the same size in surface area.

Regarding claim 42, as circuits are generally utilized to maintain electrical potentials, it is clear circuit 1402 will function as the device. Moreover, please see the discussion of this requirement in the rejection for claim 29.

Regarding claim 47, FREY et al shows the analyte to be contained in 1408 of figure 16. Moreover, with a liquid and biosamples an insulating container is inherent and necessary to the processing of the sample.

Regarding claim 48, this claim is directed to a method of operation of the sensor arrangement. The sensor arrangement, due to the use of controllable voltages, is able to operate in the condition required in claim 48. However, as the claim is to a sensor arrangement or apparatus (and since the electrode itself is taught), the examiner would like to direct attention to MPEP 2114 which states the manner of operation of the device does not differentiate an apparatus claim from the prior art.

Regarding claim 49, the circuitry shown in figure 16 of FREY et al teaches the electrodes to be connected electrically.

Regarding claim 50, FREY et al teaches at the operating electrode for functionalization to occur via the attachment of DNA in figure 16 for example.

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Moreover, FREY et al also teaches a second electrode, which can function as a counter electrode. With the output circuitry and electrolytic analyte, it is able to function as a charge carrier reservoir, as taught in paragraphs 42 and 62 of the instant application.

10. Claims 29-45, 47-49 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by HINTSCHE et al (US 5,670,031).

Regarding claims 29, 42-44, 47-49 and 51, HINTSCHE et al teaches a sensor arrangement comprising a working electrode 1, additional electrode 1 (either of the other operating electrodes or the reference electrode) and an operating circuit, as described in claim 1, maintaining any desired potential difference (as potential is controlled). A constant ratio between the potential at the working electrode and additional electrode is maintained because due to the connection of the two, as this is a system of two electrodes, the potential at both electrodes must be the same magnitude. Whether this device is an electric circuit shown (as discussed in the claims) or an insulating device which is shown as the surface 6, the broad interpretation of the device is shown in multiple places and interpretations. Furthermore, the condition of operation requiring a constant ratio of the potentials at each electrode is an operating condition and therefore does not impart any structural limitations on the apparatus. As the claims are to a sensor arrangement or apparatus, the examiner would like to direct attention to MPEP 2114 which states the manner of operation of the device does not differentiate an apparatus claim from the prior art.

Regarding claims 30 and 31, the claims are directed to the analyte to be detected, not the apparatus itself, therefore no structure is imparted to the apparatus or sensor arrangement, by the requirement of the analyte to be bound to substances with two different redox potentials. Furthermore, claim 31 is directed to a method of operation of the sensor arrangement. The sensor arrangement, due to the use of controllable voltages, is able to operate in the condition required in claim 31. However, as the claims are to a sensor arrangement or apparatus, the examiner would like to direct attention to MPEP 2114 which states the manner of operation of the device does not differentiate an apparatus claim from the prior art.

Regarding claim 32, an output is an inherent feature, as it is required to produce the graphs shown in figure 3.

Regarding claim 33, figure 1 of HINTSCHE et al also teaches the electrodes, at least a portion of the arrangement, to be shown on the substrate 8.

Regarding claim 34, figure 1 of HINTSCHE et al teaches some of the aspects of claim 29 to be on top of the substrate or external to the substrate, while others are mounted in the substrate, such as the microchannel 3-4.

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Regarding claim 35-40, there is no structural difference imparted in these discrete sensors which structurally distinguishes them from each other in terms of the components of the arrangement as stipulated in claim 29 from which they depend. HINTSCHE et al teaches an electrochemical structure (of the instant application's claim 35) and biosensor analysis (of the instant application's claims 36-38 and 40) in the abstract and in claim 4 of HINTSCHE et al.

Regarding claim 41, the operating electrodes are shown to be the same size in figure 1.

Regarding claim 45, the circuitry shown in figure 1 of HINTSCHE et al allows for the multiple concurrent readings, increasing the magnitude of the readings through multiple working or operating electrodes. This circuitry would function as the current reflector circuit required by claim 45, as both function to provide additional strength.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 43-46 and 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over FREY et al (WO 02/033397, the citations provided in this rejection are from the English translation of this document PG PUB 2004/0041717. It has been well established that English language equivalents of foreign documents are accepted forms of translation.), in view of HINTSCHE et al (US 5,670,031).

FREY et al teaches all the limitations of claims 29, 42, 47 and 49. However, FREY et al fails to teach the use of a third electrode.

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HINTSCHE et al teaches the same interdigitated approach to electrochemical detection. Regarding claim 43, HINTSCHE et al teaches a system of electrodes where there are multiple interdigitated operating electrodes as 1 in figure 1. At the time of the invention, it would have been obvious to utilize the additional electrode of FREY et al as an operating electrode, as in HINTSCHE et al because multiple measurements are able to be made concurrently ensuring accuracy and a less sensitive signal, as is described in the abstract.

Regarding claim 44, FREY et al also teaches a second electrode, which can function as a counter electrode. With the output circuitry and electrolytic analyte, it is able to function as a charge carrier reservoir, as taught in paragraphs 42 and 62 of the instant application.

Regarding claim 45, the circuitry shown in figure 1 of HINTSCHE et al allows for the multiple concurrent readings, increasing the magnitude of the readings through multiple working or operating electrodes. This circuitry would function as the current reflector circuit required by claim 45, as both function to provide additional strength.

Regarding claim 46, FREY et al teaches a source follower and one operational amplifier in figure 12, reference number 1203 as discussed in paragraph 287 for example.

Regarding claim 51, the second electrode of FREY et al can function as the constant potential electrode. The sensor arrangement, due to the use of controllable voltages, is able to operate in the condition required in claim 48. However, as the claim is to a sensor arrangement or apparatus (and since the electrode itself is taught), the examiner would like to direct attention to MPEP 2114 which states the manner of operation of the device does not differentiate an apparatus claim from the prior art.

Regarding claim 52, as is shown in HINTSCHE et al utilizing multiple electrodes to amplify the signal is known in the art. Moreover, it would have been obvious to one of ordinary skill in the art to utilize multiple or duplicate arrangements of the array of claim 29, as shown in FREY et al for more readings and in turn more accuracy or for testing multiple samples concurrently.

Regarding claim 53, it would have been obvious to layout the arrangements in an organized or matrix-like fashion as that of the multiple electrode units of HINTSCHE et al for ease of use.

Regarding claim 54, FREY et al teaches a control circuit or output in paragraph 122 to function as a readout.

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Regarding claim 55, FREY et al teaches an additional electrode with a controllable potential administered. Therefore, this electrode could function as a constant potential electrode. However, as the claim is to a sensor arrangement or apparatus (and since the electrode itself is taught), the examiner would like to direct attention to MPEP 2114 which states the manner of operation of the device does not differentiate an apparatus claim from the prior art.

Regarding claim 56, the second electrode is connected to the same circuitry as the operating electrode via the operating circuit, as shown in figure 16 of FREY et al. Therefore, the second electrode could function as a constant potential electrode. However, as the claim is to a sensor arrangement or apparatus (and since the electrode itself is taught), the examiner would like to direct attention to MPEP 2114 which states the manner of operation of the device does not differentiate an apparatus claim from the prior art.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KOURTNEY R. SALZMAN whose telephone number is (571)270-5117. The examiner can normally be reached on Monday to Thursday 6:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

krs
2/26/2010